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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/431,594 11/01/99 WHEELER

J 16303-002430

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HM22/0809

EXAMINER

LARSON, T

ART UNIT	PAPER NUMBER
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1635
DATE MAILED:

08/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/431,594

Applicant(s)

WHEELER ET AL.

Examiner

Thomas G. Larson, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-75 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 42-75 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) ✓
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 ✓

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. The continuing data section (1st paragraph) of the specification should be updated to include the patents issued from the parent applications.
2. Documents WO 95/18863 and WO 96/02655 (respectively designated AI and AL on the PTO-1449 submitted with the information disclosure statement filed 6/12/00) have been considered only to the extent possible without an English translation.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 42-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al. (USPN 5,820,873).

The claims are drawn to nucleic acid-lipid particles or pharmaceutical compositions comprising nucleic acid-lipid particles wherein the particles comprise: a nucleic acid selected from a group comprising a plasmid, a ribozyme, or an antisense oligonucleotide; a cationic lipid selected from a group that includes DODAC; a non-cationic lipid selected from a group that includes DOPE, and a PEG-

conjugated lipid that includes PEG-ceramide or PEG-phosphatidylethanolamine, wherein the conjugated lipid inhibits aggregation of the particles.

Choi et al. teach liposomes for the delivery of bioactive agents comprising DODAC, DOPE and PEG-ceramide (col. 2, ln. 66, to col. 3, ln. 15; col. 24, ln. 15, to col. 26, ln. 25; claim 24) and DODAC, DOPE, and PEG-DSPE (as per col. 3, lns. 50-51, DSPE = distearolyphosphatidylethanolamine) (col. 24, ln. 15, to col. 26, ln. 25). Choi et al. disclose liposomes having PEG-ceramide where the ceramide has 8, 14, and 20 carbons (Table II, for example). Choi et al. teach that the PEG-conjugated lipids inhibit aggregation of the liposomes (col. 24, lns. 26-32) and that the size of the liposomes ranges from 89-103 nm (col. 24, lns. 46-47). Choi et al. further disclose preparing the liposomes with 5% PEG-ceramide or 5% PEG-DSPE (col. 24, lns 18-19), and with 10% PEG-ceramide (col. 26, lns. 2-3). Choi et al. specifically teach that the bioactive agent portion of the liposome may be nucleic acids including oligonucleotides intended to "... block production of some protein within the cell" (col. 17, ln. 66, to col. 18, ln. 24; also claims 16 and 17). The genus of oligonucleotides capable of blocking expression of a protein is so small (antisense oligonucleotide, antigene oligonucleotides, and ribozymes) that the artisan of ordinary skill would at once envisage the claimed species. Therefore, disclosure the genus of oligonucleotides capable of blocking expression of a protein anticipates the ribozyme and antisense species (see MPEP 2131.02). With respect to the functions of being nuclease resistant and non-toxic, since the structural limitations of the claimed

compounds are met by the prior art compounds, the prior art compounds are presumed to have the same functional properties (see MPEP 2112.02).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is indefinite for reciting the limitation "...said cationic lipid comprises from 0% to about 20% of the lipid ...". Base claim 42, from which claim 64 depends, clearly recites the limitation that the particle of the invention "...comprises a cationic lipid...." Therefore, it cannot comprise 0% of the lipid and still meet this limitation.

7. No claim is allowed.

Art Unit: 1635

8. Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The OFFICIAL FAX numbers are (703) 308-4242 and (703) 308-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Unofficial papers, such as draft responses and proposed amendments, may be transmitted directly to the examiner's computer at (703) 746-7019. If an official paper is to be faxed to this number, it is recommended that the examiner be notified before doing so.

Any inquiry concerning this communication or earlier communications should be directed to Thom Larson, whose telephone number is (703) 308-7309. The examiner normally can be reached Monday through Friday from 9:00 AM to 5:30 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist, whose telephone number is (703) 308-0196.

Thomas G. Larson, Ph.D.
Examiner



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.